DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 April 2008 has been entered.

Status of the Claims

Claims 7-14 are pending wherein claim 7 is amended and claims 1-6 and 15-34 are canceled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7- 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,498,302).

In regards to claim 7-9, Davidson (‘302) discloses wear-resistant and surface-hardened titanium alloys that would be used as implant devices (col. 1, lines 11-20). Davidson (‘302) further discloses that the implant device surface hardness would exceed 50 HRC for titanium alloys; the alloys would have a hardness (including the core) prior to treatment of up to 40 HRC; the oxidation depth would extend to depths of 50 microns (0.002 inches) or more but would preferably be less than about 200 microns (0.0078 inches) in depth; and the depth would depend upon gas concentration, time, temperature, and alloy composition. The Examiner notes that the hardness values and hardness depth disclosed by Davidson ('302) overlaps the hardness values and hardness depth of the instant invention, which is prima facie evidence of obviousness (col. 2, line 47 – col. 3, line 16). MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected the claimed hardness values and hardness depth from the hardness values and hardness depth disclosed by Davidson (‘302) because Davidson (‘302) discloses the same utility throughout the disclosed ranges.

With respect to the recitation “having at least two layers including a TiO_2-TiO layer and an oxygen-rich layer”, the Examiner notes that Davidson ('302) discloses heating titanium alloys at about 500°C-1200°C for up to 100 hours in an oxygen-containing environment (col. 7, line 30 – col. 8, line 17), which would be the same composition and the same or a substantially similar process. Therefore at least two layers including a TiO_2-TiO layer and an oxygen-rich layer would be expected. MPEP 2112.01 I.

In regards to claims 10-12, Davidson ('302) discloses wherein the hardness of a Ti-6Al-4V alloy device decreases from the surface to the core (Figure 3).

In regards to claims 13-14, Davidson ('302) discloses that the implants would be used as orthopedic implants such as bone plates and cardiovascular implants (col. 1, lines 42-55 and col. 2, lines 11-16).

Claims 7-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al. (US 6,210,807).

In regards to claims 7-8 and 10-12, Dong et al. ('807) discloses wear-resistant titanium alloys such as Ti-6Al-4V alloys wherein oxygen would be diffused to a depth of 5 to 50 μm (0.0002 to 0.002 inches) (col. 5, lines 5-6 and Figure 6). Dong et al. ('807) further discloses that the Knoop Hardness at the surface of the alloy material would be about 900 (about 66 HRC) which decreases to about 400 at the center (about 40 HRC) (Figure 1). The Examiner notes that the hardness values and hardness depth disclosed by Dong et al. ('807) overlaps the hardness values and hardness depth of the instant invention, which is prima facie evidence of obviousness (col. 2, line 47 – col. 3, line 16). MPEP 2144.05 I. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected the claimed hardness values and hardness depth from the hardness values and hardness depth disclosed by Dong et al. ('807) because Dong et al. ('807) discloses the same utility

throughout the disclosed ranges.

Still regarding claim 7, although Dong et al. ('807) does not specify that the wear-resistant titanium alloys would have "at least two layers including a TiO_2-TiO layer and an oxygen-rich layer", Dong et al. ('807) discloses heating in a furnace containing air at 600°C for 100 hours followed by furnace cooling (col. 4, lines 20-36), which would be the same composition and the same or a substantially similar process. Therefore at least two layers including a TiO_2-TiO layer and an oxygen-rich layer would be expected. MPEP 2112.01 I.

With respect to the recitation, "titanium alloy orthopedic device" of claim 7, the Examiner notes that the shape/structure of the titanium alloy would not be limited by this recitation. Therefore, an orthopedic device has been considered an intended use of the titanium alloy. MPEP 2111.02 II.

Response to Arguments

Applicant's arguments filed 16 April 2008 have been fully considered but they are not persuasive.

The Applicant primarily argues that at column 2, lines 61-63 in Davidson ('302), it is explained that "[o]ygen diffusion hardening of titanium promotes an undesirable, weaker alpha case on the surface" and at column 6, lines 17-23, that "[i]n the case of titanium or Ti-Nb alloys, tantalum may be added as a solute, because tantalum is more reactive with oxygen (lower free energy of formation) than either titanium or niobium. Thus, it is possible to internally oxidize the alloy without oxidizing niobium or titanium if the concentration of oxygen (partial

pressure of oxygen) is less than that required to form niobium or titanium oxides." and therefore Davidson ('302) teaches away from the instant invention. In response, a known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for same use. MPEP 2123 II.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessee Roe whose telephone number is (571) 272-5938. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Roy V. King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Sheehan/
Primary Examiner, Art Unit 1793

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